

JUN 18 2010

K101440
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Section 7: Special 510(k) Summary

The following information is provided as required by 21 CFR § 807.92 for Generic Medical Device's 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor: Generic Medical Devices, Inc. (GMD)
5727 Baker Way NW, Ste. 201
Gig Harbor, WA 98332

Contact: Gail Hamilton
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Generic Medical Devices, Inc.
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Date of Submission: May 20, 2010
Proprietary Name: GMD Universal Urinary Incontinence Sling™-1012
Common Name: Mesh, Surgical, Polymeric
Regulatory Class: Class II
Product Codes: OTN
Predicate Device(s): GMD Universal Sling (K083471)
Caldera Desara™ (K072456)

Device Description:

The GMD Universal Urinary Incontinence Sling™-1012 is a sterile, single use device for the treatment of female Stress Urinary Incontinence. The Universal Urinary Incontinence Sling™-1012 is comprised of a polypropylene knitted mesh protected by a disposable polypropylene sheath with a surgical suture loop at each end for attachment of the sling to GMD's reusable T-slot trocars (sold separately). The surgical suture loop is used for inside-out / bottom-up and outside-in / top-down approaches. The method of placement and surgical approach chosen by the physician should be appropriate for the patient's diagnosis and anatomy.

Intended Use:

The GMD Universal Urinary Incontinence Sling™-1012 is intended for use in women as a suburethral sling for the treatment of Stress Urinary Incontinence (SUI) resulting from either urethral hypermobility and/or intrinsic sphincter deficiency.

The use of the device in males and children under 18 years of age is not supported by clinical studies.

Comparison to Predicate Devices:

The GMD Universal Urinary Incontinence Sling™-1012 has the same intended use and similar technological characteristics as the predicate devices: GMD Universal Sling (K083471) and Caldera Desara™ (K072456).

Non-Clinical Studies:

Bench and animal studies were performed on the GMD Universal Sling and previously submitted with the premarket notification cleared under K083471. Additional nonclinical testing was performed on the modification to the GMD Universal Sling using cadavers to prove the effectiveness of the modified sling. The data demonstrates that the GMD Universal Urinary Incontinence Sling™-1012 is substantially equivalent to the predicate device(s) and that there is no change in the safety and effectiveness due to the modification.

Conclusion:

The GMD Universal Urinary Incontinence Sling™-1012 has a similar design and the same intended use as the predicates GMD Universal Sling (K083471) and Caldera Desara™ (K072456). Biocompatibility testing and the current knowledge of the material provided by scientific literature demonstrated the appropriateness of the device materials for the proposed intended use. Bench testing demonstrates that the GMD Universal Urinary Incontinence Sling™-1012 has similar mechanical and performance characteristics as the predicate devices. Therefore, the GMD Universal Urinary Incontinence Sling™-1012 is substantially equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Generic Medical Devices, Inc.
% JWM Associates LLC
Mr. Jeff Morgan
P.O. Box 818
OCEAN SHORES WA 98569

SEP 28 2012

Re: K101440
Trade/Device Name: GMD Universal Urinary Incontinence
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated: May 20, 2010
Received: May 24, 2010

Dear Mr. Morgan:

This letter corrects our substantially equivalent letter of June 18, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

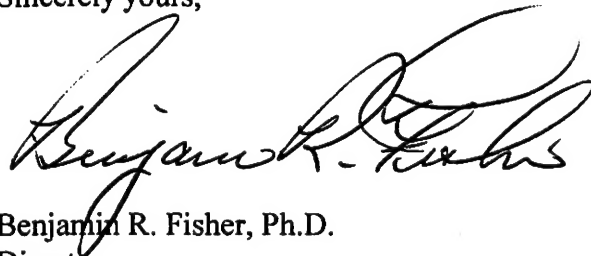
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Benjamin R. Fisher". The signature is fluid and cursive, with the first name "Benjamin" being the most prominent part.

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Section 6: Indications for Use Statement

510(k) Number:

Device Name: GMD Universal Urinary Incontinence Sling™-1012

Indications for Use:

The GMD Universal Urinary Incontinence Sling™-1012 is indicated for use in women as a suburethral sling for the treatment of Stress Urinary Incontinence (SUI) resulting from either urethral hypermobility and/or intrinsic sphincter deficiency.

The use of the device in males and children under 18 years of age is not supported by clinical studies.

Prescription Use ☒

AND/OR

Over-The-Counter Use ☐

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel Krone for Mxay
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101440

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